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UNDER SEAL

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,

Plaintiff,

v.

ARTICLES OF FINISHED AND IN-PROCESS DRUGS LISTED BELOW, WITH ANY LOT NUMBER, SIZE, OR TYPE CONTAINER, WHETHER LABELED OR UNLABELED:

C-PHEN DM DROPS
C-PHEN DM SYRUP
C-PHEN DROPS
C-PHEN SYRUP
CENTERGY DM DROPS
DEX PC SYRUP
EXPECTUSS LIQUID
GUIADRINE DX LIQUID
HISTACOL DM PEDIATRIC SYRUP
INTROL
MINTUSS DR SYRUP
PBM ALLERGY SYRUP
P CHLOR GG DROPS
PDM GG SYRUP
PHENYLEPHRINE COMPLEX LIQUID
PSEUDO COUGH
PSEUDO DM GG SYRUP
PYRICHLOR PE LIQUID
QUARTUSS DM DROPS
QUARTUSS SYRUP
TENAR DM LIQUID
TRIPLEX AD LIQUID

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Hon.

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Civil Action No. 10-

:

VERIFIED COMPLAINT FOR FORFEITURE *IN REM*

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TRIPLEX DM LIQUID
TRIPOHIST D LIQUID
TUSSAFED
TUSSAFED EX

AND

ALL OTHER ARTICLES OF DRUG, INCLUDING FINISHED AND IN-PROCESS PRODUCTS, AND DRUG COMPONENTS, INCLUDING ACTIVE AND INACTIVE INGREDIENTS, OF ANY LOT NUMBER, SIZE OR TYPE CONTAINER, WHETHER LABELED OR UNLABELED, THAT ARE DETERMINED BY THEIR LABELING OR OTHERWISE TO HAVE ORIGINATED FROM OUTSIDE THE STATE OF NEW JERSEY, AND ARE LOCATED ANYWHERE ON THE PREMISES OF TRI-MED LABORATORIES, INC., 68 VERONICA AVENUE, SUITE #1, SOMERSET, NEW JERSEY, OR ELSEWHERE WITHIN THE

JURISDICTION OF THIS COURT,

Defendants *in rem*.

Plaintiff, United States of America, by its attorney, Paul J. Fishman, United States Attorney for the District of New Jersey, by Jafer Aftab, Assistant United States Attorney, brings this verified complaint and alleges as follows in accordance with Supplemental Rule G(2) of the Federal Rules of Civil Procedure:

NATURE OF THE ACTION

1. This is a civil forfeiture *in rem* action filed by the United States of America to seize and condemn the articles set forth in the above caption (hereinafter "defendant property") for violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301, *et seq*.

THE DEFENDANTS *IN REM*

2. The defendant property consists of articles of drugs or components thereof as described in the caption. The defendant property is in the possession of Tri-Med Laboratories, Inc. ("Tri-Med" or "the firm"), 68 Veronica Avenue, Suite #1, Somerset, New Jersey, or elsewhere within the jurisdiction of this Court, which consist in whole or in part of components that were shipped in interstate commerce from outside the State of New Jersey.

JURISDICTION AND VENUE

3. Plaintiff brings this action *in rem* in its own right to condemn and forfeit the defendant property. This Court has jurisdiction over an action commenced by the United States under 28 U.S.C. § 1345, 28 U.S.C. § 1355, and 21 U.S.C. § 334.

4. Pursuant to 28 U.S.C. § 1355(b)(1), this Court has *in rem* jurisdiction because the acts giving rise to forfeiture occurred in this District and the defendant property is located in this District. Upon the filing of this complaint, the plaintiff requests that the Court issue an arrest warrant *in rem* pursuant to supplemental Rule G(3)(b)(ii), which the plaintiff will execute upon the property pursuant to Supplemental Rule G(3)(c).

5. Venue is proper in this District pursuant to 28 U.S.C. § 1395(b) and 21 U.S.C. § 334(a)(1) because the defendant property is located at Tri-Med Laboratories, Inc., 68 Veronica Avenue, Suite #1, Somerset, New Jersey.

BASIS FOR FORFEITURE

6. The defendant property is adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding do not conform to and are not operated and administered in conformity with the current good manufacturing practice (hereinafter "GMP") requirements for drugs, 21 C.F.R. Part 211. Thus, there is no assurance that the drugs meet the safety requirements of the Act and have the identity and strength, and meet the quality and purity characteristics, which they purport and are represented to possess.

7. The defendant property comprise drugs that may not be introduced or delivered for introduction into interstate commerce pursuant to the Act, 21 U.S.C. § 355(a), in that they are "new drugs" within the meaning of 21 U.S.C. § 321(p), and no approvals of applications filed pursuant to 21 U.S.C. § 355(b) are in effect with respect to such drugs, nor are there in effect notices of claimed investigational exemptions filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. § 312.

8. By reason of the foregoing, the defendant property is held illegally within the jurisdiction of this Court and is liable to seizure, forfeiture and condemnation, pursuant to 21 U.S.C. § 334.

FACTS

9. Tri-Med receives drug components in interstate commerce and uses them to custom manufacture liquid oral drugs for human use, including children and infants, and distributes them to private-label customers throughout the eastern United States and Puerto Rico.

10. FDA inspections of Tri-Med since 1997 have shown a continuing history of violations of 21 U.S.C. § 351(a)(2)(B), GMP. More recently, FDA sent an Untitled Letter to Tri-Med on July

10, 2008, identifying numerous significant GMP violations found during a February 11- March 7, 2008, inspection, and held a Regulatory Meeting with Tri-Med on August 14, 2008, to discuss those concerns. Tri-Med's representative promised that the firm would correct all deficiencies.

11. On February 23, 2010, FDA sent a Warning Letter to Tri-Med identifying continuing and similar GMP violations of 21 U.S.C. § 351(a)(2)(B) that were found during an FDA inspection on September 9-29, 2009, further advising the firm of unapproved new drug violations, 21 U.S.C. 355. FDA held a Regulatory Meeting with Tri-Med on April 15, 2010, to discuss its lack of compliance with the Act and the potential for regulatory action.

12. The most recent FDA inspection of Tri-Med, conducted May 18 – June 21, 2010, revealed continuing manufacture and distribution of these adulterated and unapproved new drugs, with continuing significant GMP violations, including, but not limited to, the following:

a. failure to establish scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, in-process materials, and drug products conform to appropriate standards of identity, strength, quality, and purity, 21 C.F.R. § 211.160(b);

b. failure to thoroughly investigate the failure of a batch or any of its components to meet its specifications, whether or not the batch has already been distributed, 21 C.F.R . § 211.192;

c. failure to establish the reliability of the suppliers' analyses through appropriate validation of the suppliers' test results at appropriate intervals, 21 C.F.R. § 211.84(d)(2);

d. failure to ensure appropriate controls are exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel, 21 C.F.R. § 211.68(b).

CLAIMS FOR FORFEITURE

COUNT I

13. Incorporated herein and made part hereof are allegations contained in paragraphs 1 through 12 of this Complaint.

14. By reasons of the foregoing, there are reasonable grounds to believe that pursuant to 21 U.S.C. § 351(a)(2)(B) of the Act, the defendant property is adulterated while held for sale after shipment of one or more of their components in interstate commerce, in that the methods used in and the facilities and controls used for, their manufacture, processing, packing, and holding do not conform to and are not operated and administered in conformity with current good manufacturing practice (GMP) requirements for drugs, 21 C.F.R. Part 211. Thus, there is no assurance that the drugs meet the safety requirements of the Act and have the identity and strength, and meet the quality and purity characteristics, which they purport and are represented to possess.

COUNT II

15. Incorporated herein and made part hereof are allegations contained in paragraphs 1 through 12 of this Complaint.

16. By reasons of the foregoing, there are reasonable grounds to believe that pursuant to 21 U.S.C. § 355(a), the defendant property are drugs which may or may not be introduced or delivered for introduction into interstate commerce, in that they are "new drugs" within the meaning of 21

U.S.C. § 321(p), and no approvals of applications filed pursuant to 21 U.S.C. § 355(b) are in effect with respect to such drugs, nor are there in effect notices of claimed investigational exemptions filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. § 312.

WHEREFORE, the United States requests that the Court issue a warrant for the arrest *in rem* for seizure of the defendant property; that notice of this action be given to all persons who reasonably appear to be potential claimants of the defendant property; that the defendant property be forfeited and condemned to the United States; that the defendant property be disposed of as this Court may direct pursuant to the provisions of the Act; and that plaintiff be awarded its costs and disbursements in this action, and for such other and further relief as this Court deems proper and just.

PAUL J. FISHMAN
United States Attorney

By: _____
JAFFER AFTAB
Assistant United States Attorney

Dated: October 6, 2010
Newark, New Jersey

VERIFICATION

STATE OF NEW JERSEY :

ss

COUNTY OF ESSEX :

I, JOSEPH F. MCGINNIS, hereby verify and declare under penalty of perjury that I am a Compliance Officer, New Jersey District Office, United States Food and Drug Administration, that I have read the foregoing Verified Complaint *in rem* and know the contents thereof, and that the matters contained in the Verified Complaint are true to my own knowledge, except that those matters herein stated to be alleged on information and belief and as to those matters I believe them to be true.

The sources of my knowledge and information and the grounds of my belief are the official files and records of the United States, information supplied to me by other law enforcement officers, as well as my investigation of this case, together with others, as a Compliance Officer, New Jersey District Office, United States Food and Drug Administration.

I hereby verify and declare under penalty of perjury that the foregoing is true and correct.

Joseph F. McGinnis
Compliance Officer
United States Food and Drug Administration

Sworn and Subscribed to
before me this 6th day
of October 2010, at Newark,
New Jersey

JAFER AFTAB, ESQ.
Attorney-at-Law
State of New Jersey